# Food and Drug Administration Center for Food Safety and Applied Nutrition Office of Special Nutritionals

ARMS#

13418



0 - FRONT

		3418	
		Complaint Number:	
	COMPLAINT/INJ	URY REPORT Date of Complaint: 2-8-99	
1. COMPLAINT INFORMATION	a. Form of complaint:  □ Telephone □ Visit □ Letter □ Other	b. Source of complaint:  Consumer	
2. INJURED PARTY AND/OR	a. Injured Party (name and address):	b. Complainant (name and address):	
COMPLAINANT	Phone (hm & wk):	Phone (hm & wk):	
INFORMATION	c. Age: 29 d. Sex: N	e. Region: f. County:	
INJURY OR ILLNESS RESULTED Yes \( \text{No} \)	a. Date/Time b. Attending Symptoms: of Onset: StyOke 12-29-7  1. Vomiting 2. Nausea 3. Diarrhea 4. Fever 5. Skin Irr. 6. Eye Irr 7. Headache 8. Other  Date/Time b. Attending		
4. PRODUCT  AND  LABELING  (as applicable)	a. Product Name: Ultimate Or c. Type Package: e. Exp/Use Date: g. Date Purchased: i. Sample ≠:	b. Product Code: d. Pkg Code/Serial #: f. Date Used: h. Amt. Remaining:	
5.  MANUFACTURER  /DISTRIBUTOR INFORMATION	a. Manuracturer (name and address)  Phone:	b. Distributor/Retailer (name and address)  Phone:	
6. COMPLAINT OR INJURY	a Nature of Complaint/Injury  Adulterated Illness/Injury  Sanitation Misbranded  C Follow-up Yes No	b. Valid Yes No  Tampering Other  d. Notice Yes No Days	
OFFICE USE ONLY ASSIGNED TO INVEST.:	e. Description of Complaint/Injury: Son Suffered massive Stroke Ofter taking "Uttimate		
DIVISION / BRANCH: DYUGS INJURY CLASS:	Drange" (contains lphe	•	
REVIEWER'S INITIALS:	Sel	attached e-mail from	
DATE REVIEWED:		MM. 000001	
7. DISPOSITION:	•		
8. REFERRED TO: 9. DATE REFERRED:		9. DATE REFERRED:	
10 NAME AND TITLE.		11. DATE INVESTIGATED:	

From:
Date: Thu, 31 Dec 1998 08:38:58 EST
To:
Subject: Ma Huang

Dear Dr.

Thank you for your article. My son is 29 yrs old and has just suffered a massive stroke after ingesting a dose of "Ultimate Orange", an OTC supplement containing ma huang. He is currently in intensive care at

He is just 29, but has been in the military since age 19. He was attached to the and was in perfect health. He was out of the Army to complete his college and was due to graduate in May of 1999. He has already received his letter of acceptance from the Army as a 2nd Lt., and was scheduled to attend officer training school.

At the time of the stroke, he had been running on a treadmill for 15 minutes, felt a sharp pain to his head and passed out. The prognosis is not very good at this time and due to the severe brain damage and dead brain cells he may never walk again and will certainly not be able to follow his dream of a career in the military.

I am looking for some direction to get the word out to the media and to the public about the effects of this drug. Any help you could provide would be greatly appreciated.

My office number is and my fax is

Thank you,

Home:

February 12, 1999

# FILE CON

Dear Mr.	

This is a follow up to our telephone conversation, earlier today.

My son, is 29 years of age. On December 29, 1998 while running on a treadmill at a local fitness club, he felt a sharp pain above his right eye and then passed out. He was transported to the later came to, but was paralyzed on his left side. A few hours later, he regained the feeling on his left side, leading the doctors to believe that for some reason, the main artery feeding the right side of his brain had become constricted, stopping the flow of blood. But, the problem had reversed and he was finally getting blood flow through the artery. They scheduled at MRI for the next day at 1:00 p.m.

The next day, he seemed fine, walking, talking, eating and ready to get out of the hospital. However, prior to the MRI, he suffered a massive stroke to the right side of his brain, again leaving him paralyzed on the left side. The MRI was completed, verifying that he had, in fact, had a massive stroke, resulting in the death of the majority of the right side of his brain.

He was immediately transferred by ambulance to in for further treatment. While at result, he would undergo three major brain surgeries over the next four days.

He was in a coma, contracted pneumonia, was unable to eat or speak much of the time.

According to the doctors, my son had almost died several times during the ordeal.

After removing the majority of my son's right brain area, they were finally able to get the swelling under control. They then had to do a fourth brain surgery to put in a shunt, to drain the excess brain fluid to the stomach.

My son was finally transferred from the ICU to the floor of the hospital and is currently in Room of waiting for a transfer to a rehabilitation hospital.

His current condition is not very good. He is still paralyzed on the left side, he has not been able to get out of bed since December 30, 1998, and he has to have someone feed him. Due to the paralysis he has trouble talking and swallowing. Due to the brain injury he has trouble staying awake and is also confused. He can not get out of bed, so he must wear a "diaper" and is forced to use the bathroom in his pants and then wait for someone to change him. This is a 29 year old man!

Prior to the injury, he had been attending as a full time student in an Army program called, This a is program where an enlisted man receives a special release from his current enlistment contract in order to complete his education, while being enrolled in the ROTC program. The enlisted man is then accepted back into the Army as an Officer. His most recent enlistment was to be completed in the year 2002. According to the ROTC, if my son had not finished his obligation of completing his education, then it would have been mandatory for him to complete his enlistment in the Army and then be eligible for discharge in the year 2002.

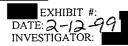
My son was scheduled to graduate from in May of this year, and had already had a letter from the Army confirming his acceptance as an Officer. According to the ROTC, the Army will not provide my son with any benefits and will simply "forget" about their contract with him. The ROTC, at is being very helpful and is willing to do anything they can to see that my son does receive the benefits to which he should be entitled. They are pushing this case through the Army channels and requesting an exception to the ruling. They are all comrades of my son's and will do anything necessary to help him and his family. My son is married to and they have a four-year-old son,

My son joined the Army, just after graduating from high school and had decided to make the Army his career. At the time of his "conditional discharge" to complete the program, he had attained the rank of or He was in the and another for and another for At the time of his injury he was ranked in the top 5% of military personnel in the Army ROTC.

He had a great and rewarding future ahead of him. The Army and the United States have lost a great asset and someone that would have been a great officer. It is unthinkable that after dedicating himself to the U.S. Army, that they would just throw him away when it was not convenient for the Army.

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In order to stay fit for the Army, my son was taking a legal supplement - "Ultimate Orange" (I have attached an information sheet on the product for your review). The product had been purchased on the Army Post, at The main ingredient is "Ephedrine" also known as "My Huang". The attending doctor at



documented that this supplement was probably the cause of the stroke. I have attached several articles about Ephedrine and My Huang, but basically it is just old-fashioned "SPEED"!!

While the doctors at would not say the cause of the stroke was Ephedrine, they did state that they had ruled out all other "normal" causes that were seen in 85% of the cases of strokes. I have also spoken to several doctors and they all seem to be aware of the drug Ephedrine and the harm that it causes, I feel they would be available to provide letters or verbal testimony as to the harmfulness of the drug. Ephedrine is a "vaso constrictor", and it is my opinion that the main blood vessel to my sen's brain had completely clamped shut, causing the first stroke. As the blood vessel was shut down for several hours, the blood clot started to form, later in the day the blood started to flow again, allowing my son to regain use of his left side. However, the next morning, the blood clot broke loose, travelling through the artery and becoming clogged at a vessel junction, thus causing the massive stroke from which my son now suffers.

I want to be able to accomplish the following:

- > Put people on notice about the dangers of the drug Ephedrine,
- > Have the United States Army do what is right and provide benefits to one of their soldiers, and
- > Obtain a large settlement from the makers of "Ultimate Orange", so that my son and his family will be able to survive the rocky and treacherous road ahead.

My son's family does not have any money to pay attorney's fees and without him working, they are worried about losing their home and car. My son was working part-time at

My son will need to find an attorney that can see the merits of this case and would be willing to take the case on a contingency fee. My friend, suggested that you might be just the attorney that could make things right.

Thank you for your time and understanding.

Sincerely,



000005





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# American Emporium

## **Next Nutrition Ultimate Orange**

1 lb. / 16 servings container

Contains a proprietary blend of nutrients and herbs for workout energy.

#### **ULTIMATE ORANGE**

Considered by some athletes to be the most powerful workout drink ever developed.

One serving of ULTIMATE ORANGE and you'll feel the difference. It's like no other drink available today. ULTIMATE ORANGE contains a proprietary blend of nutrients and herbs for hard working muscles. It is the perfect drink to use before and during workouts when you need maximum energy.

### When to drink ULTIMATE ORANGE

Before exercise - Drink one serving for body weight 30 - 45 minutes prior to exercise. During exercise - Take sips between reps or sets or every 15 - 20 minutes throughout workout. Avoid gulps all at once. For extra energy - Drink one serving for body weight 30 minutes before you feel tired.

### How much ULTIMATE ORANGE should you drink?

Follow the table below as a guideline of usage amounts versus body weight. Each person has a unique metabolism that may require a slightly smaller or larger serving size for preferred effects.

Bodyweight LBS 132 154 176 198 220 Bodyweight KG 60 70 80 90 100 Number of Scoops 1/2 1/2-3/4 1 1-1 1/2 1 1/2

#### MIXING INSTRUCTIONS

Place 1 level scoop in glass, add 8 fl.oz./1 cup water, stir and drink. ULTIMATE ORANGE mixes quickly with a few stirs of a spoon. There is no need for a blender. To fill 16 fl.oz. water bottle - place 2 scoops in water bottle, half fill with water, shake vigorously, and then fill to top with water.

NUTRITIONAL INFORMATION

Serving size 28.4 g/ 1 oz. (1 level scoop) Servings per container 16 101 Protein 7g Carbohydrates 16 g

الواران المهرجية

Fat 1g Cholesterol 0 Sodium 75 mg

Potassium 220 mg

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NUTRITIONAL INFORMATION PER SERVING % RDA Protein 7 g 15 Vitamin A 2500 iu 50 Vitamin C 50 mg 80 Vitamin B1[thiamine] 70 mcg 50



Vitamin B2 [riboflavin] 85 mcg 50 Niacin 10 mg 50 Calcium 200 mg 20 Iron 360 mcg 20 Vitamin D 56 iu 15 Vitamin E 30 iu 80 Vitamin B6 8 mg 400 Folic acid 200 mcg 50 Vitamin B12 5 mcg 80 Phosphorous 175 mg 15 lodine 70 mcg 50 Magnesium 140 mcg 30 Zinc 12 mg 50 Copper 260 mcg 15 Biotin 140 mcg 50 Pantothenic acid 40 mg 400 Chromium 25 mcg \*\* Molybdenum 30 mcg Selenium 20 mcg \*\* Manganese 2 mg

Choline 75 mg

Inositol 75 mg

Ma Huang [ephedra] 415 mg

ESSENTIAL AMINO ACIDS

- L leucine [BCAA] 640 mg
- L isoleucine [BCAA] 365 mg
- L valine [BCAA] 261 mg
- L lysine 478 mg
- L threonine 428 mg
- L methionine 129 mg
- L phenylalanine 211 mg
- L tryptophan 98 mg

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All complete proteins contain L - tryptophan. No manufactured L - tryptophan has been added.

#### **INGREDIENTS**

QUADRACARB [4 stage release carbohydrate from branching chain glucose polymers from amylopectins, high glycemic index maltose with dextrose, plus low glycemic index fructose], LACTOPRO [high biological value, low lactose Lactoglobulin, Lactalbumin, Lactoferrin and Immunoglobulin protein fractions from enzymatically treated and filtered, low fat, whey protein concentrate], BioVite [bioactive vitamin-mineral blend of potassium phosphate, calcium carbonate, magnesium oxide, zinc gluconate, potassium succinate, vitamin E acetate, ascorbic acid, calcium pantothenate, choline, inositol, molybdenum aspartate, selenium aspartate, manganese gluconate, ferrous fumarate, boron tri-citrate-aspartate-glycinate, potassium iodide, retinyl palmitate, pyridoxine HCI, niacin, riboflavin, thiamine,





chromium arginate, biotin, ergocalciferol, cyanocobalamin, betacarotene, ferrous succinate, chromium picolinate], citric acid, ULTIMATE ORANGE HERBAL CONCENTRATE [a proprietary herbal powder blend from Ma Huang, Guarana Seed, Green Tea, Siberian Ginseng, and Bioflavanoids from orange peel], Structured Lipid Complex [medium chain triglycerides with omega-3 fatty acids], Xylitol, natural flavors, lecithin, cellulose gum, xanthan gum, food coloring.

NNUO \$17.95



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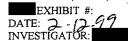


Ultimate Orange: The most powerful workout drink ever developed. One serving and you'll feel the difference. Ultimate Orange contains a proprietary blend of nutrients and herbs for hard-working muscles. It is the perfect drink to use before and during exercise, and whenever an energy boost is needed. Important Notice: Seek advice from a health care practitioner prior to use, especially if you are pregnant or nursing, or have high blood pressure, heart or thyroid disease, diabetes, difficulty in urination due to enlarged prostate, or if taking an MAO inhibitor or any other prescription drug. Ultimate Orange Serving Size: 1 scoop (1oz) Servings per Container: 16 Amount Per Serving Vitamins & Minerals % RDA Calories 101 Phosphorous...175mg 15% Calories from fat 9 Iodine...70mcg 50% Fat 1g Magnesium...40mcg 30% Cholesterol 0mg Zinc...12mg 50% Sodium 75mg Copper...260mcg 15% Potassium 220mg Carbohydrates 16g Also provides Protein 25g Chromium 25mcg Molybdenum 30mcg Vitamins & Minerals % RDA Choline 75mcg Vitamin A...2500iu 50% Manganese 2mg Vitamin C...50mg 80% Selenium 20mcg Calcium...200mg 20% Inositol 75mg Iron...360mcg 20% MaHuang (ephedra) 415mg Vitamin D...56iu 15% Vitamin E...30iu 80% Essential Amino Acids Thiamin...70mcg 50% L-leucine (BCAA) 640mg Riboflaven...85mcg 50% L-isoleucine (BCAA) 365mg Niacin...10mg 50% L-valine (BCAA) 261mg Vitamin B6...8mg 400% L-lysine 478mg Folic Acid...200mcg 50% L-threonine 428mg Vitamin B12...5mcg 80% L-methionine 129mg Biotin...140mcg 50% L-phenylalnine 211mg Pantothenic Acid...40mg 400% Ltryptophan 98mg Recommended Use: Use 30-45 minutes before exercise, during exercise, and whenever extra energy is needed.

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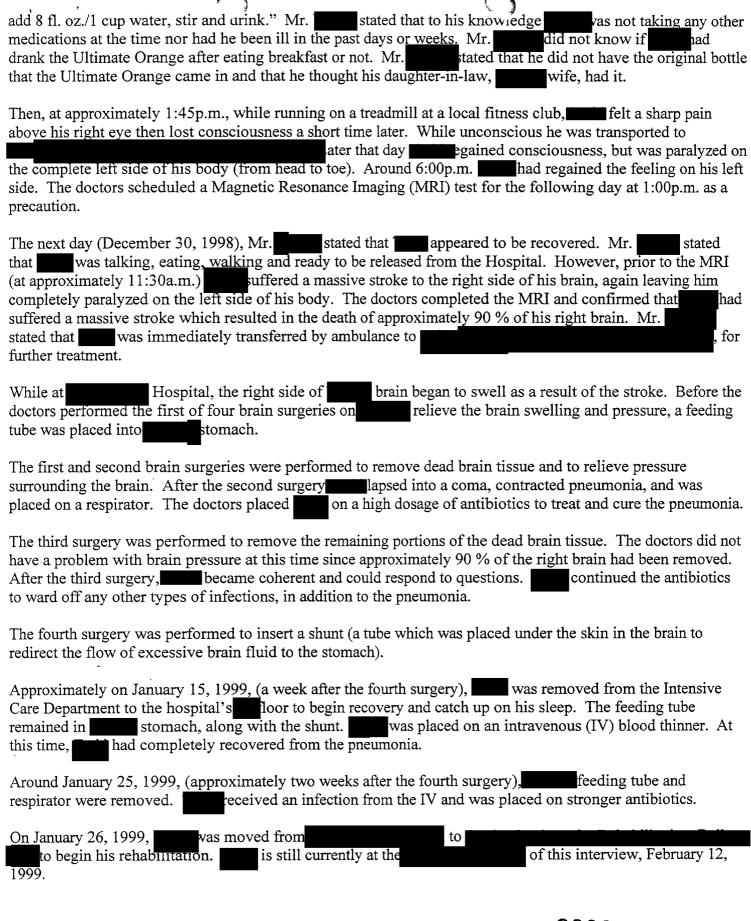
PMS#	13418
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Firm Name:  Location:  City, State, Zip:	Complaint #	Date: February 12, Inv. Name:	, 1999
he would like to obtain a cop on Fe	Drug Investigator for the On February 7, 1999, y of the proposed ephedrine rule ebruary 25, 1999, regarding the had suffere	received an e-mail from es and to be scheduled as a sp	Mr. that stated eaker before the board also stated
SUMMARY OF FINDINGS On February 8, 1999, I receive obtain further information res		ail and was assigned to intervi- Ultimate Orange product.	ew Mr. to
On February 12, 1999, I met	with Mr. his place of	business	
had been attending the called . This enlistment contract in order t man is then accepted back in	ey had a five year old son,	as a full time student d soldier receives a special release being enrolled in the ROTC particles school is completed.	hat prior to the injury t in an Army program ease from this current program. The enlisted was scheduled to
energy" and that it is "consid	ng). had purchased the pr	most powerful workout drink	provided ge product t is for "workout ever developed." Mr.
Also from the Internet, Mr. from the United States Food System's reports (exhibit #	and Drug Administration (FDA	rch results for Ultimate Orang  A) Special Nutritionals Adverse  Refing ephedrine containing pre	e Event Monitoring
	on December 29, 1998, differention contains mixing instr		

000010

2-12-99

dated 2-8-99, Complainant: Mr.



000011

dated 2-8-99, Complainant:

Mr. stated that the attending physician at Hospital documented in file that the Ultimate Orange was the probable cause of the stroke. Mr. stated that while the physicians at Hospital would not say the cause of the stroke was the Ultimate Orange, they did stated that they had ruled out all other normal causes that are seen in 85 % of stroke cases. Mr. stated that he had been discussing his son's condition with a Board Certified Acupuncturist named (Mr. stated that Mr! had e-mailed him on information regarding Mu Huang (exhibit #
Mr. stated that, in his opinion, the ephedrine constricted the flow of blood to his son's brain which caused the strokes. Mr. stated that his son has taken the same dosage of Ultimate Orange in the past, with no troubles. Mr. stated that his son has also consumed "Andro-6" without any side effects.
Mr. provided me with copies of newspaper articles related to ephedrine (exhibit # exhibit # and a picture of his son in the program (exhibit # exhibit # exh
Mr. stated that as of this interview (February 12, 1999) he had not obtained legal council; even though he had mailed a letter to Mr. Attorney at Law, discussing the case (exhibit #
I provided Mr. with a copy of the proposed ephedrine rules. Mr. stated that he would be at the February 25, 1999, phedrine public hearing
I left Mr. with two copies of the Authorization for Medical Records Disclosure form and two copies of the FDA Authorization for Medical Records Disclosure form to give to Mrs.  Stated that due to condition, his wife was acting as legal guardian; therefore, she would be able to sign the forms. I provided Mr. with Mrs.  Sign the forms had been signed. Mr. did not have the names of the hospitals.
Mrs. obtained the forms from Mr. and mailed them to me on February 25, 1999 (attachment #s & I contacted all three medical hospitals to obtain a copy of medical records on February 26, 1999. was told by all three hospitals that they would also need a copy of the Power of Attorney (which gives wife the power to act as his legal guardian). I called and left a message for Mr. on February 26, 1999, at 8:00a.m., informing him that I would need a copy of this document and social security number to obtain medical records from the hospitals.
As of today, February 26, 1999, 11:30a.m., I had not received a return call from Mr of Attorney document.
main phone #: medical records fax #:  ** medical records department stated that they could accept the medical records authorization form faxed to them along with the Power of Attorney document, birth, and social security number.

**000012** 2-12-99

main phone #
medical records department phone #: fax #:
** medical records department stated that they could accept the medical records
authorization form faxed to them along with the Power of Attorney document, date of birth, and social security number.
main phone #:
rehabilitation department phone #:
authorization form mailed to them along with the Power of Attorney document, date of
birth, and social security number.
Date of Birth:
Home address:
Home phone #:
Home phone #: Work phone #:
EXHIBITS:  Internet information on Ultimate Orange product.
<ul><li>Next Nutrition, Inc. corporate information.</li><li>Internet information on Ultimate Orange from FDA's SN/AEMS reports.</li></ul>
) Internet information on additional products which contain ephedrine.
E-mail copy from Mr. Acupuncturist.  Newspaper clippings regarding ephedrine products and the second
) Letter from Mr. to Mr. Attorney at Law.
ATTACHMENTS:
1.) Leading FDA Authorizations for Medical Records Disclosure. 2-3.) Complaint desired dated 2-8-99, and fax from Mr. Leading on February 7, 1999.
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000013

Complaint ated 2-8-99, Complainant: Mr. Page 4 of 4

2-12-99